

## **II. Claim Rejections - 35 USC § 102**

Claims 62-70, 72, and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by Singh et al. (2003/0235549).

Singh discloses dental compositions including a moisture responsive gel carrier (e.g. hydrogel) comprise a moisture sensitive polymer (para [0029, 0031, 0035]), and water-soluble salts and a therapeutic agent (e.g. whitening agent and para [0007]). The "that increases in viscosity upon contact with moisture ..." is not given any patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recited the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness, but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478,481 (CCPA 1951). Singh further discloses thermally responsive polymers, such as methyl cellulose and ethyl cellulose ([0085]), pH sensitive polymer [0023] and hydrogen peroxide [0007, 00168]; carbamide peroxide and water [0174]); carboxypolymethylene, polyvinylpyrrolidone [0152].

Applicant respectfully traverses the rejection.

In paragraph [0023], Singh et al. (2003/0235549) disclose a "composition comprising a water-swellaable, water-insoluble polymer, a blend of a hydrophilic polymer and a complementary oligomer capable of hydrogen bonding or electrostatic bonding to the hydrophilic polymer. An active agent such as a tooth whitening agent may also be included. In one embodiment, the composition further comprises a second water-swellaable, water-insoluble polymer that has different pH solubility characteristics than the first water-swellaable, water-insoluble polymer." See paragraph [0023]. In

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paragraph [0029], Singh et al further disclose a “method for preparing a hydrogel film suitable for incorporation into an oral care, transmucosal or transdermal composition or system is provided. This method comprises preparing a solution or a gel of the first and second water-swellaable, water-insoluble polymers, a hydrophilic polymer, and a complementary oligomer capable of hydrogen bonding or electrostatic bonding to the hydrophilic polymer, in a solvent; depositing a layer of the solution on a substrate to provide a coating thereon; and heating the coated substrate to a temperature in the range of about 80.degree. C. to about 100.degree. C. for a time period in the range of about 1 to about 4 hours, thereby providing a hydrogel film on the substrate.”

Thus, the invention relates to a solution and the coating and heating of the solution on a substrate to a temperature high enough to dry the solution to form a dried film. This disclosure merely teaches that the viscosity increases as the composition becomes more concentrated caused by drying and is in contrast to the present invention of claim 62, which recites in relevant parts: “a moisture responsive gel carrier comprising a moisture sensitive polymer complex and a water soluble salt; and a therapeutic agent dispersed in the responsive gel carrier; wherein said dental composition increases in viscosity upon contact with moisture following application to an oral cavity surface.” (Emphasis added)

These remaining paragraphs [0031]-[0035] discuss how a dried film is moistened to become sticky, as follows:

“[0031] The method further comprises loading the hydrogel film with an active agent such as a whitening agent, thereby providing a tooth whitening composition.

[0032] The adhesive compositions of the invention provide a number of significant advantages relative to the prior art. In particular, the present compositions:

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[0033] (1) provide ease of handling;

[0034] (2) are readily modified during manufacture so that properties such as adhesion, absorption, translucence, and swelling can be controlled and optimized;

[0035] (3) can be formulated so that tack increases or decreases in the presence of moisture so that the composition is not sticky until moistened..."

These paragraphs again show that Singh et al are teaching away from the present invention.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Applicant respectfully submits that Singh et al do not disclose or teach the inventions of claim 62 and claim 62 is patentable over Singh et al. (2003/0235549).

Claims 63-78 are dependent from claim 62 and are also rejected under 35 U.S.C. §102(b) as being anticipated by Singh et al. (2003/0235549). While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 62. The dependent claims include all of the limitation of the base claims and any intervening claims, and recite additional features that further distinguish them from the

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cited references. Therefore claims 63-78 are also patentable over Singh et al. (2003/0235549) for at least the same reasons as noted above for claim 62.

Applicant respectfully requests that the rejection of claims 62-78 under 35 U.S.C. §102(b) as being anticipated by Singh et al. (2003/0235549) be withdrawn. Reconsideration is respectfully requested.

### **III. Claim Rejections - 35 USC § 103**

Claims 71, 73, 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh as applied to claim 62 above. Singh discloses the invention substantially as claimed except for the specifics of moisture responsive gel carrier and water soluble salt, e.g. sodium chloride. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the specific amount of moisture responsive gel since it has been held that discovering the optimum or workable ranges involves only routine skills in the art. In re Aller, 105 USPQ 233. Further, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the amount of the gel based on how responsive the gel is needed. Accordingly, if one desires to make the gel less moisture responsive, then one of ordinary skill in the art at the time of the invention was made to realize to lower the amount of moisture responsive carrier. Further, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to use alternatives of water soluble salts (e.g. sodium chloride) for stabilizing purpose. Further, since methylcellulose and poly (oxyethylene )-poly block copolymer are art equivalent, one of ordinary skill in the art would have found obvious to substitute methylcellulose with poly (oxyethylene )-poly block copolymer.

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Applicant respectfully traverses the rejection.

As noted above, Singh et al. (2003/0235549) disclose and teach what generally happens when a composition is dried: it increase in viscosity and if coated on a substrate, it becomes a film. This is teaching away from the present invention of claim 62, as also noted above.

Three criteria must be met to establish a prima facie case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

Applicant respectfully submits that since Singh et al. (2003/0235549) teach away from the present invention of claim 62, and teaching away rebuts the obviousness rejection. Therefore, claim 62 is patentable over Singh et al. (2003/0235549) under 35 U.S.C. 103(a).

Claims 63-78 are dependent from claim 62 and are also rejected under 35 U.S.C. §103(a) as being unpatentable over Singh et al. (2003/0235549). While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 62. The dependent claims include all of the limitation of the base claims and any intervening claims, and recite additional features that further distinguish them from the cited references. Therefore claims 63-78 are also patentable over Singh et al. (2003/0235549) for at least the same reasons as noted above for claim 62.

Applicant respectfully requests that the rejection of claims 62-78 under 35 U.S.C.

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§103(a) as being unpatentable over Singh et al. (2003/0235549) be withdrawn.

Reconsideration is respectfully requested.

#### IV. New Claims

New claims 102-175 are added. Support for these new claims is found throughout the specification. No new matter is added.

These claims are also related to moisture responsiveness of increasing viscosity in a more humid environment and are therefore also patentable over Singh et al. (2003/0235549) for at least the same reasons as noted above for claim 62-78. Favorable action is respectfully requested.

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V. Conclusion

In view of the amendments and remarks set forth above, Applicant respectfully submits that the application is in condition for allowance and early notice thereof is respectfully solicited.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-621-6415.

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Respectfully submitted,

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